

Michael Thomas Margolis, M.D.

Page 1

1 IN THE DISTRICT COURT
2 95th JUDICIAL DISTRICT
3 DALLAS COUNTY, TEXAS
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5

6 LINDA BATISTE,

7 Plaintiff,

8 -vs-

No. DC-12-14350

9 JOHN ROBERT McNABB, M.D.,

JOHNSON & JOHNSON, and

10 ETHICON, INC.,

11 Defendants.
_____/

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15 DEPOSITION OF MICHAEL THOMAS MARGOLIS, M.D.
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17

18 DATE: November 26, 2013

19 TIME: 9:08 a.m.

20 LOCATION: Pulone Reporting Services, Inc.
1550 The Alameda
21 Suite 150
San Jose, California 95126

22 REPORTED BY: Diane S. Martin, CSR 6464, CCRR
23
24
25

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<p style="text-align: right;">Page 82</p> <p>1 little bit? I mean, a site on my website?</p> <p>2 MR. FREESE: Do you mean like a link?</p> <p>3 BY MR. BROWN:</p> <p>4 Q. Do you have a reference?</p> <p>5 A. References.</p> <p>6 Q. Let me restate it then.</p> <p>7 Do you have a reference on your website that</p> <p>8 shows the Burch is the gold standard for stress urinary</p> <p>9 incontinence?</p> <p>10 A. A reference list? I don't think I have quoted</p> <p>11 or published a reference list.</p> <p>12 Q. Doctor, you know at times that you make a</p> <p>13 statement and then you put a reference below; is that</p> <p>14 correct?</p> <p>15 A. In publications you do so, that is correct.</p> <p>16 Q. And my question to you is, do you have a</p> <p>17 reference on your website that supports the statement</p> <p>18 that the Burch is the current gold standard for stress</p> <p>19 urinary incontinence?</p> <p>20 A. I ever -- I do not have a reference list on my</p> <p>21 website.</p> <p>22 Q. You don't have a reference at all?</p> <p>23 A. Correct. No reference.</p> <p>24 Q. Doctor, please identify for me the article</p> <p>25 that says that Burch is the current gold standard?</p>	<p style="text-align: right;">Page 84</p> <p>1 THE WITNESS: Well, I'm going to hold to my</p> <p>2 prior answer.</p> <p>3 BY MR. BROWN:</p> <p>4 Q. Which is that you can't do it as you sit here</p> <p>5 today; correct?</p> <p>6 A. I'm not going to speculate and give you an</p> <p>7 incorrect answer. I won't speculate.</p> <p>8 Q. Doctor, you told us yesterday that you read</p> <p>9 literature every day; right?</p> <p>10 A. I do.</p> <p>11 Q. And you have the statement on here that says</p> <p>12 "the 'gold standard' is the procedure for stress</p> <p>13 urinary incontinence." It's the gold standard and you</p> <p>14 can't state to me one article today as we sit here that</p> <p>15 says that the Burch is the current gold standard?</p> <p>16 MR. FREESE: All right. First of all, I</p> <p>17 object. It's argumentative. It's been asked three</p> <p>18 times and answered. And apparently you just don't</p> <p>19 accept his answer.</p> <p>20 So I'm going to instruct you not to answer the</p> <p>21 question. It's argumentative.</p> <p>22 MR. BROWN: Okay. Then I'll restate it.</p> <p>23 BY MR. BROWN:</p> <p>24 Q. Can you identify an article in the last five</p> <p>25 years that says that the Burch is the current gold</p>
<p style="text-align: right;">Page 83</p> <p>1 A. I can --</p> <p>2 MR. FREESE: Object to the form of the</p> <p>3 question.</p> <p>4 Go ahead.</p> <p>5 THE WITNESS: I can get you articles that</p> <p>6 support that position.</p> <p>7 BY MR. BROWN:</p> <p>8 Q. As you sit here today, Doctor, can you point</p> <p>9 to an article that says that the Burch is the current</p> <p>10 gold standard?</p> <p>11 MR. FREESE: Object to the form of the</p> <p>12 question.</p> <p>13 THE WITNESS: I'll stick with my answer. I</p> <p>14 can get you articles that support that position.</p> <p>15 BY MR. BROWN:</p> <p>16 Q. That's not my question, Doctor. My question</p> <p>17 to you --</p> <p>18 A. Well, I can't give you off the top of my head</p> <p>19 right now a direct quote. There are plenty of articles</p> <p>20 and -- but I can't quote one to you directly.</p> <p>21 Q. Can you identify as you sit here today an</p> <p>22 article in the last five years that has said that Burch</p> <p>23 is the current gold standard?</p> <p>24 MR. FREESE: Object to the form of the</p> <p>25 question.</p>	<p style="text-align: right;">Page 85</p> <p>1 standard for stress urinary incontinence as you sit</p> <p>2 here today?</p> <p>3 MR. FREESE: Object to the form of the</p> <p>4 question. Asked and answered.</p> <p>5 Go ahead and answer.</p> <p>6 THE WITNESS: I'm going to hold to my prior</p> <p>7 answer.</p> <p>8 BY MR. BROWN:</p> <p>9 Q. Which is?</p> <p>10 A. You know, the same that I gave before.</p> <p>11 Q. Yes, you can, no you can't, or "I don't know,"</p> <p>12 Doctor?</p> <p>13 A. Okay.</p> <p>14 MR. FREESE: Object to the form of the</p> <p>15 question. Asked and answered.</p> <p>16 THE WITNESS: As I've stated already, I'll be</p> <p>17 happy to get you some articles, but I don't have one</p> <p>18 that I can quote right now because I don't want to</p> <p>19 speculate or give you an inaccurate answer.</p> <p>20 BY MR. BROWN:</p> <p>21 Q. Okay. Doctor, can you identify any of the</p> <p>22 major professional organizations that we discussed</p> <p>23 earlier that identify Burch as the current gold</p> <p>24 standard for stress urinary incontinence?</p> <p>25 MR. FREESE: Object. Asked and answered.</p>

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<p style="text-align: right;">Page 90</p> <p>1 Q. Let me restate that. 2 If you'll go back to the first page, please. 3 Under number 1. The second sentence says, "Neither the 4 FDA advisory panel, the NIH, the American College of 5 Obstetrics and Gynecology, ACOG, nor AUGS has 6 recommended removing any mesh products from the market 7 or withholding them from surgeon use." 8 Do you agree that's in the position statement? 9 A. Where is that? I'm sorry. 10 MR. FREESE: It's right here. 11 THE WITNESS: Oh, I'm sorry. I see it. 12 Yes. 13 BY MR. BROWN: 14 Q. Do you disagree or agree with that, Doctor? 15 A. That's what they wrote. 16 Q. No. I'm asking you, do you disagree with that 17 statement or do you agree with it? 18 A. I don't disagree that that's what they wrote. 19 Q. Doctor, that's not what I'm asking you. 20 A. Well, I'm misunderstanding you. 21 Q. I'm asking you, in your training, experience 22 and education do you agree as you sit here today with 23 the statement that we just read? 24 A. I don't disagree that neither the FDA advisory 25 panel, the NIH, the ACOG or AUGS has recommended</p>	<p style="text-align: right;">Page 92</p> <p>1 and documents, internal documents, I think they should 2 be removed. 3 BY MR. BROWN: 4 Q. Doctor, if you'll turn to page 3. You see 5 where it says in the first sentence under number 5, do 6 you see where it says, "2011 FDA warning"? 7 A. Correct. 8 Q. Do you see where it says "the 2011 FDA 9 warning, however, the warning was about transvaginal 10 mesh for prolapse." 11 Do you see that? 12 A. Correct. 13 Q. Do you agree or disagree that the 2011 FDA 14 warning was only about transvaginal mesh for prolapse? 15 MR. FREESE: Object to the form of the 16 question. 17 THE WITNESS: They are accurate that that's 18 what the FDA warning in 2011 was about. 19 BY MR. BROWN: 20 Q. About transvaginal meshes for prolapse only? 21 A. Correct. 22 Q. Doctor, you agree that the full-length 23 midurethral slings including TVT-O were excluded from 24 post marketing studies? 25 MR. FREESE: Object to the form of the</p>
<p style="text-align: right;">Page 91</p> <p>1 removing any mesh. That what they state is factually 2 correct. 3 Q. Okay. Do you agree or disagree that mesh 4 products for stress urinary incontinence should be 5 withheld from surgeon use? 6 A. Transvaginal synthetic mesh materials, I 7 assume you're referring to? 8 Q. Yes. 9 A. I think -- I believe that once an accurate and 10 thorough understanding of all the pros and cons and all 11 of the literature and data on these materials is known 12 to everyone, including the failure to warn of all the 13 risks, that most physicians will choose not to use it 14 and will come to the conclusion that they should not be 15 used. 16 Q. Doctor, my question to you -- 17 A. And should be pulled from the market. 18 Q. Do you as you sit here today believe that 19 transvaginal midurethral synthetic slings should be 20 removed from the market? 21 MR. FREESE: Object to the form of the 22 question. Asked and answered. 23 Go ahead and answer it again. 24 THE WITNESS: "Most" would include me. So 25 knowing what I know, having reviewed all of the data</p>	<p style="text-align: right;">Page 93</p> <p>1 question. 2 THE WITNESS: I believe that's accurate. 3 BY MR. BROWN: 4 Q. Are you aware of the FDA requesting Ethicon to 5 provide additional post-marketing studies for its TVT 6 Obturator? 7 A. Not that I'm aware of. 8 Q. Doctor, if you continue to go down I'm looking 9 at the last sentence where it says, "Full-length 10 midurethral slings, both retropubic and transobturator, 11 have been extensively studied, are safe and effective, 12 relative to other treatment options, and remain the 13 leading treatment option and current gold standard of 14 care for stress urinary incontinence surgery." 15 You agree that that is accurately read in the 16 AUGS position statement? 17 A. That is an accurately read opinion of those 18 who wrote this position statement, which is a minority 19 of the AUGS members. So yes, it is accurately read. 20 Q. Your testimony is that this is a minority of 21 the AUGS members? 22 A. Well, whoever wrote this is a small -- I mean, 23 the entire body of AUGS didn't write this. A small 24 cadre of individuals, members of AUGS wrote this, 25 right?</p>

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<p style="text-align: right;">Page 102</p> <p>1 MS. REMINGTON: A comfort break. 2 MR. BROWN: Sure. 3 (Recess taken.) 4 BY MR. BROWN: 5 Q. Doctor, does literature today identify another 6 procedure as the gold standard? 7 A. Yes. I think there is some. 8 Q. And what is that procedure, Doctor? 9 A. The Burch. 10 Q. Are there other studies that identify the 11 midurethral slings as the current gold standard? 12 A. There are those who argue it. That's their 13 opinion. 14 Q. Is the answer to my question yes, Doctor? 15 A. There are those who say so. 16 Q. So just so I have a clean question here, is 17 there literature that identifies the midurethral sling 18 as the current gold standard? 19 MR. FREESE: Object to the form of the 20 question. 21 You may answer. 22 THE WITNESS: There are documents which you 23 have, of course, already brought to my attention that 24 say so, so the answer is yes. 25 BY MR. BROWN:</p>	<p style="text-align: right;">Page 104</p> <p>1 BY MR. BROWN: 2 Q. Let me ask you that then. 3 A. It's not a bill. It was a resolution that 4 failed. 5 Q. Just so I understand it correctly, this 6 resolution that you were a proponent for failed; is 7 that correct? 8 A. That is correct. 9 Q. And, Doctor, do you know if the AUGS board of 10 directors strongly opposed your resolution 105-12? 11 MR. FREESE: Object to the form of the 12 question. 13 THE WITNESS: I believe they did. 14 BY MR. BROWN: 15 Q. Do you know if SUFU -- what is SUFU, S-U-F-U? 16 A. The Society for Urodynamic study. You know -- 17 Urodynamic Female Urology, something like that. 18 Q. Doctor, do you know if the ACOG board opposed 19 resolution 105-12? 20 A. One individual from ACOG, the vice president, 21 wrote a letter opposing it. And by the way, the 22 president of AUGS opposed it. 23 I don't know actually if the board opposed 24 it. I do know that a letter was written from AUGS 25 president and from ACOG vice president, both of which</p>
<p style="text-align: right;">Page 103</p> <p>1 Q. Is the TVT Obturator a midurethral sling? 2 A. The TVT Obturator is a midurethral sling. 3 Q. Doctor, are you familiar with a California 4 resolution 105-12? 5 A. Can you read it for me? 6 Q. I'll give it to you. 7 (DEFENDANT'S EXHIBIT 12 WAS MARKED.) 8 THE WITNESS: I am familiar with this 9 document. 10 BY MR. BROWN: 11 Q. Doctor, were you the proponent of this 12 resolution? 13 A. I was a co-proponent. Dr. Reeves Chalmers, 14 R-e-e-v-e-s, last name C-h-a-l-m-e-r-s, was the 15 co-author. 16 Q. Doctor, did the AUGS board of directors 17 strongly oppose this resolution? 18 MR. FREESE: Object to the form of the 19 question. 20 THE WITNESS: Members of the CMA house of 21 delegates who represented AUGS and who refused to 22 acknowledge their financial support did oppose this 23 resolution, which did, by the way, fail. So this is 24 actually technically not a resolution because it 25 failed.</p>	<p style="text-align: right;">Page 105</p> <p>1 opposed it, but I don't know about their board. 2 So I guess to be clear on the prior answer and 3 this answer, those individuals wrote letters opposing 4 it, but I don't know about the boards. 5 (DEFENDANT'S EXHIBIT 13 WAS MARKED.) 6 BY MR. BROWN: 7 Q. Doctor, I'm handing you Exhibit 13. 8 I believe you stated in your designation that 9 you gave testimony at the FDA; is that correct? 10 A. That is correct. 11 Q. And I believe that testimony was September 8, 12 2011? 13 A. Correct. 14 Q. I believe this was on your reliance list; is 15 that correct, Doctor? 16 A. I hope so. 17 Q. If not, we'll make it. 18 A. I appreciate that. 19 MR. FREESE: We're going to do a battlefield 20 supplemental. 21 BY MR. BROWN: 22 Q. Doctor, again, I'm not trying to be 23 sarcastic. Not trying to insult your intelligence 24 here, but -- 25 A. It wouldn't take much insulting.</p>

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<p style="text-align: right;">Page 114</p> <p>1 commonly studied procedure using mesh for stress 2 urinary incontinence repair is the TVT procedure? 3 A. The most commonly studied procedure using mesh 4 for SUI is the TVT? Probably so. 5 Q. Doctor, do you agree or disagree that there 6 are at least 80 RCTs with at least one arm randomized 7 for surgical mesh for the treatment of SUI? 8 A. I agree that there are that many articles. 9 Q. Has the FDA that you're aware of ever stated 10 that the Burch has unparalleled high success rates? 11 MR. FREESE: Are you asking if he's ever said 12 that? 13 MR. BROWN: The FDA. 14 MR. FREESE: Oh. 15 THE WITNESS: I'm not aware of the FDA stating 16 that. 17 BY MR. BROWN: 18 Q. Are you aware that the FDA came out with an 19 executive summary for the September 8th and 9th, 2011 20 conference that you attended? 21 MR. FREESE: I'm sorry, would you ask that 22 question again, Michael? 23 BY MR. BROWN: 24 Q. Yes. Are you aware that the FDA had an 25 executive summary for the September 8th and 9th, 2011</p>	<p style="text-align: right;">Page 116</p> <p>1 Q. Do you see that, Doctor? 2 A. I do. 3 Q. And you stated, "I hope the FDA will, through 4 firm action, help save others from the painful 5 experiences that thousands of unfortunate women have 6 had to suffer through so far." 7 Did I accurately read that? 8 A. Yes, you do, thank you. 9 Q. And were you proposing that midurethral 10 synthetic slings be taken off the market? 11 A. Ultimately I was hoping that they would do so. 12 Q. Are you finished, Doctor? 13 A. Yes. 14 Q. And that's what I'm asking. Were you 15 proposing that the FDA take the TVT off the market? 16 A. At the time I was hoping that they would study 17 it more, get more information from industry, from every 18 available source, and come to the conclusion that we 19 are arguing here today, that they should be removed 20 from the market. 21 Q. And you were arguing that they should be 22 removed from the market, the midurethral synthetic 23 slings; correct? 24 MR. FREESE: Objection. Asked and answered. 25 THE WITNESS: I'm going to stick with my</p>
<p style="text-align: right;">Page 115</p> <p>1 FDA meeting that you attended? 2 A. It was a hearing, actually. And I believe 3 they did. And I testified at the hearing. Not 4 attended. So ... 5 Q. I think, Doctor, you identify number 5 on your 6 reference list as the FDA executive summary; is that 7 correct? 8 A. You know, yes. I'm pretty sure. Okay. 9 Thanks. Thank you. 10 Q. So that's a document that you've reviewed 11 before; correct, Doctor? 12 A. Yes. Though I haven't kept it -- though I 13 haven't put it to memory, no. 14 Q. Doctor, are you aware of any statement that 15 has come from the FDA that says that there are high 16 complication and low success rates for midurethral 17 synthetic slings? 18 A. I can't quote you any FDA source as I sit 19 here. 20 Q. Doctor, if you look on the -- your FDA 21 presentation, if you'll go to the second-to-last page. 22 The I guess you'd say second-to-last paragraph starts 23 with the sentence, "I hope." 24 Do you see that? 25 A. Second to last sentence, I see.</p>	<p style="text-align: right;">Page 117</p> <p>1 answer I already gave. 2 BY MR. BROWN: 3 Q. I'm not sure I understand the second part. I 4 think you said "we." And so what I'm doing is 5 asking -- 6 A. Did I say we? 7 MR. BROWN: Can you read back? I think you 8 said "we" and I just want to make sure. 9 THE WITNESS: No, I don't think I said "we." 10 Did I? 11 MR. FREESE: You were saying in French, yes. 12 (Record read by the court reporter as follows: 13 "A: At the time I was hoping that they would 14 study it more, get more information from 15 industry, from every available source, and 16 come to the conclusion that we are arguing 17 here today, that they should be removed from 18 the market.") 19 MR. FREESE: He's saying "we," as in you and 20 he are arguing. 21 THE WITNESS: Right. Thank you. 22 MR. FREESE: So if you want to ask the 23 question again now, I'll just object. So the answer is 24 clear. 25 THE WITNESS: That you and I are -- yeah,</p>

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<p style="text-align: right;">Page 118</p> <p>1 that's what I meant.</p> <p>2 BY MR. BROWN:</p> <p>3 Q. I'm not sure what you meant, which is why I'm</p> <p>4 trying to ask it. So let me ask my question again.</p> <p>5 MR. FREESE: Let him ask the question again.</p> <p>6 He'll start over.</p> <p>7 THE WITNESS: All right.</p> <p>8 BY MR. BROWN:</p> <p>9 Q. Were you proposing or arguing that the</p> <p>10 midurethral synthetic slings should be taken off the</p> <p>11 market in your presentation to the FDA?</p> <p>12 MR. FREESE: Object to the form of the</p> <p>13 question.</p> <p>14 Go ahead.</p> <p>15 THE WITNESS: Well, again, you keep on calling</p> <p>16 it presentation. It was testimony. But yes.</p> <p>17 BY MR. BROWN:</p> <p>18 Q. Okay. And the FDA did not mandate that</p> <p>19 midurethral slings should be taken off the market; is</p> <p>20 that correct?</p> <p>21 A. As of yet they have not.</p> <p>22 Q. Okay. And specifically, the FDA has not</p> <p>23 mandated that the TVT Obturator be removed from the</p> <p>24 market; is that correct?</p> <p>25 A. As of yet they have not.</p>	<p style="text-align: right;">Page 120</p> <p>1 answer that you believe so?</p> <p>2 A. Whatever I said. But I would like to see that</p> <p>3 document.</p> <p>4 MR. BROWN: Would you read it back?</p> <p>5 MR. FREESE: I think what he's trying to do,</p> <p>6 Michael, is to find context to the sentence.</p> <p>7 (Record read by the court reporter as follows:</p> <p>8 "Q: To your recollection, Doctor, do you</p> <p>9 remember saying that the FDA got caught with</p> <p>10 their pants down?")</p> <p>11 MR. FREESE: That's a good sign. He's putting</p> <p>12 stuff back in that red rope of his.</p> <p>13 MR. BROWN: Maybe.</p> <p>14 MR. FREESE: Oh, no, another one.</p> <p>15 THE WITNESS: There goes lunch.</p> <p>16 (Discussion off the record.)</p> <p>17 BY MR. BROWN:</p> <p>18 Q. Doctor, is it still your position today as you</p> <p>19 sit here that the Burch procedure is the procedure of</p> <p>20 choice for most patients, given its unparalleled high</p> <p>21 success rates of approximately 90 percent nationwide?</p> <p>22 A. Absolutely.</p> <p>23 Q. Is it your position, Doctor, that the Burch</p> <p>24 has higher success rates than the TVT?</p> <p>25 A. Yes.</p>
<p style="text-align: right;">Page 119</p> <p>1 Q. Today, Doctor, has the FDA mandated that the</p> <p>2 TVT Obturator be taken from the market?</p> <p>3 A. As of yet, they have not. That would be up to</p> <p>4 right this moment.</p> <p>5 Q. Doctor, did you make a statement right after</p> <p>6 the FDA hearing that the FDA got caught with their</p> <p>7 pants down? My question is, did you make that</p> <p>8 statement?</p> <p>9 A. I think that's accurate. I think I was called</p> <p>10 back up to the microphone, and they asked me some</p> <p>11 questions after my presentation. I'm sure you have the</p> <p>12 quote in front of you. I actually would like to hear</p> <p>13 what I said.</p> <p>14 Q. To your recollection, Doctor, do you remember</p> <p>15 saying that the FDA got caught with their pants down?</p> <p>16 MR. FREESE: Objection. Asked and answered.</p> <p>17 He's asked you to see what you're referring to. You</p> <p>18 can show it to him or not.</p> <p>19 THE WITNESS: Can I see the document so I can</p> <p>20 answer?</p> <p>21 BY MR. BROWN:</p> <p>22 Q. I'm just asking if you remember that, Doctor?</p> <p>23 A. I've answered the question. Now I'd like to</p> <p>24 see the document that you're referring to.</p> <p>25 Q. I might have missed your answer, but is your</p>	<p style="text-align: right;">Page 121</p> <p>1 Q. Can you, as you sit here today, point to a</p> <p>2 study that says that the Burch has unparalleled high</p> <p>3 success rates, or words to that effect?</p> <p>4 A. Those are already in my statement.</p> <p>5 Q. Maybe I didn't ask that appropriately.</p> <p>6 Can you point to a study that states that the</p> <p>7 Burch procedure has unparalleled high success rates?</p> <p>8 A. I can, but not as I sit here right now.</p> <p>9 Q. Okay.</p> <p>10 A. I will get them for you. Plus they're also in</p> <p>11 my -- whatever my -- whatever these documents are</p> <p>12 called.</p> <p>13 Q. Your reliance list?</p> <p>14 A. Thank you.</p> <p>15 Q. And, Doctor, it's interesting that you bring</p> <p>16 that up because I read through every document on your</p> <p>17 reliance list.</p> <p>18 A. Cool.</p> <p>19 Q. And I couldn't find one that said that the</p> <p>20 Burch had unparalleled high success rates, or words to</p> <p>21 that effect.</p> <p>22 MR. FREESE: Okay. Well, first of all, I</p> <p>23 object to that.</p> <p>24 MR. BROWN: Well, let me --</p> <p>25 MR. FREESE: Okay. You're right. Go ahead.</p>

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<p style="text-align: right;">Page 126</p> <p>1 So in answer to your question, everything I've 2 said about the Burch applies to the MMK, just to save 3 time. 4 BY MR. BROWN: 5 Q. Sure. So am I accurate in saying according to 6 your website, when it says that the Burch has 7 unparalleled high success rates, approximately 90 8 percent, that that would also apply to MMK? 9 A. Yes, sir. 10 Q. Doctor, are you aware of success rates sharply 11 declining after five years with the MMK? 12 A. They don't sharply decline. 13 Q. Is there an average, in your opinion, decline 14 of success after five years for MMK? 15 A. The ten-year success rate for the MMK/Burch is 16 in the 90 percent range. 17 Q. Did you say ten year? 18 A. The ten year. 19 Q. Have you seen studies, Doctor, that show that 20 the MMK has success rates around 58 percent at ten 21 years? 22 A. If you have a study you would like to quote, 23 I'm sure I'd be happy to review it. I'm sure there are 24 studies that say that. 25 Q. All right, Doctor, do you still have Exhibit</p>	<p style="text-align: right;">Page 128</p> <p>1 Q. Doctor, you know a lot of times that in 2 peer-reviewed publications, they'll have a conclusion 3 section? 4 A. Correct. 5 Q. And oftentimes they'll -- strike that. 6 Are you aware of any peer-reviewed published 7 literature that indicates that the TVT is not 8 effective? 9 MR. FREESE: Object to the form of the 10 question. 11 THE WITNESS: Well, sure. I mean, the studies 12 that I argue showing all the TVT complications are in 13 effect saying it's not effective. 14 BY MR. BROWN: 15 Q. What study is that, Doctor? 16 A. Well, we can go over if you want, and I can 17 pull some articles and come back with the exact quotes 18 for you, but I mean, I argued with references that the 19 TVT has a high complication rate, and a low success 20 rate, and I can get those articles and lay them out for 21 you again. So I mean, if you give us a little time. 22 But there's plenty of data in peer-reviewed journal, 23 RCT included, of studies showing that the TVT has got 24 issues. 25 Q. Doctor, as you sit here today can you point to</p>
<p style="text-align: right;">Page 127</p> <p>1 10 in front of you, which is your website? 2 A. Okay. 3 Q. All right, Doctor, I'm now on your third 4 paragraph. Do you see where it says, "Well-publicized 5 high complication and low success rates of synthetic 6 slings"? 7 A. I do. 8 Q. And is that still your position today? 9 A. Yes. 10 Q. Doctor, have you ever seen a study that says 11 that the TVT is not safe? 12 MR. FREESE: Object to the form of the 13 question. 14 MR. BROWN: Let me restate it then. 15 BY MR. BROWN: 16 Q. Doctor, are you aware of a peer reviewed -- 17 strike that. 18 Doctor, are you aware of a peer-reviewed 19 publication that indicates that the TVT is not safe? 20 A. We've gone through a lot of articles that 21 discuss the complications associated with the TVT. Has 22 any one of them said the TVT is not safe, 23 quote/unquote? I can't give you an answer to that. 24 I don't know of any study as I sit here now 25 that says, quote/unquote, the TVT is not safe.</p>	<p style="text-align: right;">Page 129</p> <p>1 a study that says that the TVT is not effective? 2 MR. FREESE: Object to the form of the 3 question. 4 THE WITNESS: I'll get them for you. As I've 5 just described. I'll be happy to bring them back, and 6 we'll go through them one at a time. 7 BY MR. BROWN: 8 Q. Doctor, respectfully, I didn't ask you if you 9 could get them. I said, as you sit here today can you 10 point to a study that says that the TVT is not 11 effective? 12 MR. FREESE: Object to the form of the 13 question. 14 THE WITNESS: As I sit here at this moment, at 15 this moment I don't have an article in front of me for 16 you at this moment. 17 BY MR. BROWN: 18 Q. Doctor, do you think over the lunch break you 19 could identify a study that says that the TVT is not 20 safe or effective? 21 A. I will do what I can. 22 MR. FREESE: Well, I object to that. So we 23 provided you reliance lists. Those documents are 24 available to you. 25 MR. BROWN: Well, Rich, I reviewed them and I</p>

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<p style="text-align: right;">Page 150</p> <p>1 they're falling out of favor.</p> <p>2 Q. So currently at the medical institutions that</p> <p>3 you teach and train at, the midurethral synthetic sling</p> <p>4 is taught; is that correct?</p> <p>5 A. Correct.</p> <p>6 Q. Doctor, are you going to testify that</p> <p>7 polypropylene causes sarcomas or cancer in humans?</p> <p>8 MR. FREESE: Object to the form of the</p> <p>9 question.</p> <p>10 THE WITNESS: In humans?</p> <p>11 BY MR. BROWN:</p> <p>12 Q. Yes.</p> <p>13 A. That it does cause sarcomas in humans? Was</p> <p>14 that your question?</p> <p>15 Q. Yes, sir.</p> <p>16 A. I don't have evidence to -- to that effect.</p> <p>17 So no.</p> <p>18 Q. Is your sole testimony with regard to the</p> <p>19 material safety data sheets, that Ethicon didn't</p> <p>20 disclose that information to physicians?</p> <p>21 A. Well, that's not my sole testimony. My sole</p> <p>22 testimony is that Ethicon has failed to disclose a</p> <p>23 whole laundry list of complications and potential</p> <p>24 complications. Failure to warn of significant risks,</p> <p>25 and we'll, I'm sure, go into those risks shortly.</p>	<p style="text-align: right;">Page 152</p> <p>1 A. I do. Implantation, sorry.</p> <p>2 Q. Yeah.</p> <p>3 Doctor, do you believe that the rat studies</p> <p>4 correlate to what occurs in humans?</p> <p>5 A. I believe that animal studies are very</p> <p>6 important when studying materials and drugs,</p> <p>7 particularly materials, and that any mammal response to</p> <p>8 a material should be considered in the warning labels.</p> <p>9 So yes, I think animal studies, and particularly this</p> <p>10 animal study should be at least considered and put open</p> <p>11 to the public for consideration.</p> <p>12 Q. Doctor, are you aware of any literature that</p> <p>13 says that the results of the rat study transferrable to</p> <p>14 humans -- let me state it this way. Strike that.</p> <p>15 Are you aware of any literature that states</p> <p>16 that the results of the rat study transferrable to</p> <p>17 humans and can -- strike it again. Sorry.</p> <p>18 Are you aware that Dr. Klinge and</p> <p>19 Klosterhalfen have stated that the rat study is not</p> <p>20 transferrable to humans?</p> <p>21 MR. FREESE: Object to the form of the</p> <p>22 question.</p> <p>23 THE WITNESS: Could you give me a direct</p> <p>24 quote?</p> <p>25 BY MR. BROWN:</p>
<p style="text-align: right;">Page 151</p> <p>1 Q. We will, so let me narrow down my question</p> <p>2 then.</p> <p>3 Do you have any clinical evidence that</p> <p>4 polypropylene causes sarcomas in humans?</p> <p>5 A. I have no literature to substantiate that.</p> <p>6 Q. Do you -- let me mark this document. I'm</p> <p>7 going to hand you Exhibit 16. It's the MSDS sheet that</p> <p>8 was on your reliance list.</p> <p>9 (DEFENDANT'S EXHIBIT 16 WAS MARKED.)</p> <p>10 THE WITNESS: Thanks.</p> <p>11 MR. BROWN: That's 16, Rich.</p> <p>12 MR. FREESE: Thank you.</p> <p>13 BY MR. BROWN:</p> <p>14 Q. This is one of the MSDS sheets that's on your</p> <p>15 reliance list; is that correct?</p> <p>16 A. Correct.</p> <p>17 Q. I assume you've reviewed it before?</p> <p>18 A. I have.</p> <p>19 Q. If you'll go to the last page. Do you see</p> <p>20 where it says that polypropylene has been tested in</p> <p>21 laboratory rats by subcutaneous implementation of disc</p> <p>22 or powder?</p> <p>23 A. Yes.</p> <p>24 Q. And it says local sarcomas were induced at the</p> <p>25 site of implementation?</p>	<p style="text-align: right;">Page 153</p> <p>1 Q. I will.</p> <p>2 A. Okay, cool.</p> <p>3 (DEFENDANT'S EXHIBIT 17 WAS MARKED.)</p> <p>4 MR. BROWN: Rich, we'll supplement it for a</p> <p>5 clean copy, but I'm going to have to give him a</p> <p>6 highlighted copy if that's fine with you.</p> <p>7 MR. FREESE: Sure, that's fine. No problem</p> <p>8 with me.</p> <p>9 (Discussion off the record.)</p> <p>10 A. Okay.</p> <p>11 Q. Doctor, how about we look at it together?</p> <p>12 A. Okay, sure.</p> <p>13 Q. Doctor, I've handed you Exhibit 17; is that</p> <p>14 correct?</p> <p>15 A. Correct.</p> <p>16 Q. Doctor, we're looking at the back, which is</p> <p>17 page 260, and it says, "Finally, one decisive question</p> <p>18 remains. Are the results of the rat study</p> <p>19 transferrable to humans, and can surgical meshes induce</p> <p>20 malignancies after long-term implementation in decades</p> <p>21 in our hernia patients? The answer is no."</p> <p>22 Did I read that correctly?</p> <p>23 A. Correct.</p> <p>24 Q. Do you agree or disagree with that statement?</p> <p>25 A. I disagree.</p>

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<p style="text-align: right;">Page 170</p> <p>1 urinary incontinence.</p> <p>2 Q. Even severe stress urinary incontinence?</p> <p>3 A. Including severe.</p> <p>4 Q. Doctor, is there a midurethral sling that is</p> <p>5 safer than the TVT Obturator?</p> <p>6 MR. FREESE: Object to the form of the</p> <p>7 question.</p> <p>8 THE WITNESS: I'd have to look at the data on</p> <p>9 all the TVT-O competitors, which I don't have in front</p> <p>10 of me to answer that accurately.</p> <p>11 BY MR. BROWN:</p> <p>12 Q. So as of right now you don't know?</p> <p>13 A. As of this moment I do not know.</p> <p>14 Q. Doctor, let's move to the instructions for</p> <p>15 use. And you might have already answered this</p> <p>16 yesterday and if you did, I apologize, but have you</p> <p>17 ever participated in the drafting of an instructions</p> <p>18 for use?</p> <p>19 MR. FREESE: Object to the form of the</p> <p>20 question. It was asked at length yesterday.</p> <p>21 Go ahead and answer it again.</p> <p>22 THE WITNESS: Other than my lecturing or</p> <p>23 testifying to the FDA and lecturing all over the</p> <p>24 country, I have not.</p> <p>25 BY MR. BROWN:</p>	<p style="text-align: right;">Page 172</p> <p>1 BY MR. BROWN:</p> <p>2 Q. Do you know if the symptoms of an adverse</p> <p>3 reaction are required by the FDA to be identified in an</p> <p>4 instructions for use?</p> <p>5 A. That's kind of splitting hairs; isn't it? I</p> <p>6 mean, adverse reaction by definition is going to have</p> <p>7 the symptoms in it.</p> <p>8 I can't really answer your question the way</p> <p>9 you've asked it. That doesn't really make sense.</p> <p>10 MR. BROWN: Well, read it back if you don't</p> <p>11 mind because I'm asking you about if the FDA requires</p> <p>12 it. So I want to know if you know if the FDA requires</p> <p>13 it or not, but you can read it back?</p> <p>14 THE WITNESS: The specific symptoms associated</p> <p>15 with adverse reactions.</p> <p>16 MR. BROWN: If you'll just let her read mine</p> <p>17 back and answer that question.</p> <p>18 (Record read by the court reporter as follows:</p> <p>19 "Q: Do you know if the symptoms of an adverse</p> <p>20 reaction are required by the FDA to be</p> <p>21 identified in an instructions for use?")</p> <p>22 MR. FREESE: Object to the form of the</p> <p>23 question. I think it's -- I think it's</p> <p>24 incomprehensible but --</p> <p>25 THE WITNESS: I don't understand that</p>
<p style="text-align: right;">Page 171</p> <p>1 Q. Doctor, what is the FDA requirement for</p> <p>2 adverse reactions that are required to be placed into</p> <p>3 an instructions for use, if you know?</p> <p>4 MR. FREESE: Object to the form of the</p> <p>5 question.</p> <p>6 THE WITNESS: In a word that all potential</p> <p>7 adverse events be written so that surgeons and patients</p> <p>8 can make informed decisions. All warnings be made</p> <p>9 open.</p> <p>10 BY MR. BROWN:</p> <p>11 Q. Is that the FDA requirement?</p> <p>12 A. Well, that's not their words. I mean, just in</p> <p>13 summary, they require that adverse reactions be</p> <p>14 reported.</p> <p>15 Q. Doctor, I'm not talking about reporting. I'm</p> <p>16 talking about an IFU. Let me restate my question.</p> <p>17 A. Well, reported in the IFU. Noted or listed in</p> <p>18 the IFU.</p> <p>19 Q. Do you know the specific FDA requirement for</p> <p>20 what adverse reaction should be in an instructions for</p> <p>21 use?</p> <p>22 MR. FREESE: Object to the form of the</p> <p>23 question.</p> <p>24 THE WITNESS: I can't quote it to you word for</p> <p>25 word as I sit here right now.</p>	<p style="text-align: right;">Page 173</p> <p>1 question. That doesn't make sense to me.</p> <p>2 MR. FREESE: And I don't want to quibble, but</p> <p>3 are you saying is a fever a symptom of a fever and</p> <p>4 therefore you have to disclose the fever as the symptom</p> <p>5 of a fever? I don't understand it.</p> <p>6 MR. BROWN: Will you just object and then let</p> <p>7 him --</p> <p>8 MR. FREESE: I'm sorry. I object.</p> <p>9 BY MR. BROWN:</p> <p>10 Q. Doctor, do you know if the FDA requires that</p> <p>11 the symptoms be identified --</p> <p>12 MR. FREESE: Object to the form of the</p> <p>13 question.</p> <p>14 BY MR. BROWN:</p> <p>15 Q. -- in an instructions for use?</p> <p>16 A. As I sit here, I don't know if the symptoms</p> <p>17 are required.</p> <p>18 Q. Doctor, do you agree that the instructions for</p> <p>19 use is written for physicians?</p> <p>20 A. I do.</p> <p>21 Q. And that -- strike that.</p> <p>22 The physician is to use his training -- strike</p> <p>23 that.</p> <p>24 The physician is to use his or her training,</p> <p>25 experience and education in conjunction with the</p>

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<p style="text-align: right;">Page 202</p> <p>1 Q. Doctor, have you ever attended Ethicon's</p> <p>2 professional education program for TVT?</p> <p>3 A. No.</p> <p>4 Q. Have you attended Ethicon's professional</p> <p>5 education program for any pelvic floor repairs?</p> <p>6 A. No.</p> <p>7 Q. Have you reviewed Ethicon's professional</p> <p>8 education video on the TVT Obturator incontinence</p> <p>9 procedure?</p> <p>10 A. I've reviewed the videos on everything that's</p> <p>11 out there published. All -- all of the devices that</p> <p>12 have videos that are open to the -- that are posted on</p> <p>13 the Web, I've watched.</p> <p>14 Q. Let me just -- if you say, "I've already</p> <p>15 answered it," that's fine, but have you watched a video</p> <p>16 from Ethicon's professional education on the TVT</p> <p>17 Obturator?</p> <p>18 A. I believe I have. If it's on the Web, I've</p> <p>19 seen it. I've seen -- I've seen all the videos. And</p> <p>20 if it's available on the Web, then I've seen it. I</p> <p>21 mean, I've watched every single video that is out</p> <p>22 there, and if TVT is on that list, I believe I've seen</p> <p>23 it.</p> <p>24 Q. And does the Ethicon professional education</p> <p>25 video have an instructor walking through the steps</p>	<p style="text-align: right;">Page 204</p> <p>1 scanning electron microscope or any other kind of</p> <p>2 microscope to assess degradation?</p> <p>3 A. No.</p> <p>4 Q. Have you ever assessed any polypropylene mesh</p> <p>5 under scanning electron microscope or any other kind of</p> <p>6 microscope to assess degradation?</p> <p>7 A. No.</p> <p>8 Q. Doctor, are you aware if Ethicon has an</p> <p>9 antioxidant package for its polypropylene mesh?</p> <p>10 A. No.</p> <p>11 Q. Are you saying no, they do not, or no, you do</p> <p>12 not know?</p> <p>13 A. I do not know.</p> <p>14 Q. Do you know if an antioxidant blend with the</p> <p>15 polypropylene affects the potential for degradation in</p> <p>16 a polypropylene mesh?</p> <p>17 A. Could you repeat that question? That was a</p> <p>18 little confusing.</p> <p>19 MR. BROWN: I'm going to have to ask you to do</p> <p>20 that.</p> <p>21 (Record read by the court reporter as follows:</p> <p>22 "Q: Do you know if an antioxidant blend with</p> <p>23 the polypropylene affects the potential for</p> <p>24 degradation in a polypropylene mesh?")</p> <p>25 MR. BROWN: Let me restate that. I said</p>
<p style="text-align: right;">Page 203</p> <p>1 verbally?</p> <p>2 A. As I recall, though I can't recall specifics,</p> <p>3 it did.</p> <p>4 Q. Doctor, do you know if Ethicon has a</p> <p>5 professional education called the advanced users forum</p> <p>6 that teaches and trains on the management of</p> <p>7 complications?</p> <p>8 A. I do not.</p> <p>9 MR. BROWN: Would you read back my question,</p> <p>10 because I'm not even sure what I asked exactly. I</p> <p>11 apologize.</p> <p>12 (Record read by the court reporter as follows:</p> <p>13 "Q: Doctor, do you know if Ethicon has a</p> <p>14 professional education called the advanced</p> <p>15 users forum that teaches and trains on the</p> <p>16 management of complications?")</p> <p>17 BY MR. BROWN:</p> <p>18 Q. Doctor, I'm going to talk about degradation.</p> <p>19 Have you performed any studies on mesh</p> <p>20 degradation?</p> <p>21 A. No.</p> <p>22 Q. Have you published any studies on mesh</p> <p>23 degradation?</p> <p>24 A. No.</p> <p>25 Q. Have you ever assessed a TVT mesh under</p>	<p style="text-align: right;">Page 205</p> <p>1 polypropylene I think too many times.</p> <p>2 BY MR. BROWN:</p> <p>3 Q. Doctor, do you know if an antioxidant blend</p> <p>4 that is incorporated in the polypropylene may prevent</p> <p>5 degradation?</p> <p>6 A. No.</p> <p>7 Q. You don't know; is that correct?</p> <p>8 A. I don't know that it does.</p> <p>9 Q. Are you saying that it does not, or that you</p> <p>10 don't know if it does?</p> <p>11 A. I do not know if it does.</p> <p>12 Q. Doctor, can you identify any studies that</p> <p>13 degradation with the TVT has any clinical significance</p> <p>14 if degradation exists?</p> <p>15 A. There are internal documents that I've</p> <p>16 reviewed, and there are the clinical correlates to what</p> <p>17 has been described in the internal documents of mesh as</p> <p>18 it has protruded through the vagina after having been</p> <p>19 broken down. But I don't know of any studies.</p> <p>20 Q. Let me ask you this, Doctor: Is it your</p> <p>21 opinion that the TVT mesh degrades?</p> <p>22 A. Yes.</p> <p>23 Q. Is it your opinion that degradation that you</p> <p>24 believe occurs with the TVT has clinical significance?</p> <p>25 A. Yes.</p>

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<p style="text-align: right;">Page 206</p> <p>1 Q. And what is that clinical significance, 2 Doctor?</p> <p>3 A. It breaks down. It is found eroded through 4 the vaginal wall at various locations. It causes -- 5 its breakdown causes an increase in the chronic foreign 6 body reaction that is seen in pristine mesh. And I do 7 have concerns that it might be found in other parts of 8 the body as a result of the breakdown.</p> <p>9 Q. Doctor, have you seen any clinical data that 10 the potentially degraded mesh is found in other parts 11 of the body?</p> <p>12 A. Other than the eroded -- or, rather, the 13 eroded mesh particles seen -- mesh fragments, that is, 14 seen, which is commonly reported in the literature, no.</p> <p>15 Q. Are you talking about the mesh that degrades 16 into the vagina, is that what you're talking about, 17 Doctor?</p> <p>18 A. Correct.</p> <p>19 Q. Are you aware of any mesh degradation 20 particles that are found in other places besides the 21 vaginal canal?</p> <p>22 A. No.</p> <p>23 Q. Doctor, can you identify any literature that 24 the degradation of polypropylene -- restate that. 25 Doctor, do you have any clinical literature</p>	<p style="text-align: right;">Page 208</p> <p>1 diligence, including a conversation with a physician. 2 Q. Do you provide patient brochures to your 3 patients?</p> <p>4 A. Well, since I don't put these implants in, I 5 do not.</p> <p>6 Q. Do you provide patient brochures for any 7 device or -- well, let me ask you this: Do you use any 8 device that would have a patient brochure?</p> <p>9 A. I don't know that Xenform has a brochure. It 10 might. But I don't know if they do, and I don't use 11 it.</p> <p>12 Q. Do you know the pore size of the Prolene mesh?</p> <p>13 A. I know that it's claimed to be macroporous.</p> <p>14 Q. Doctor, do you disagree that it's macroporous?</p> <p>15 A. I think as applied to the patient, it shrinks 16 up, it's microporous, but --</p> <p>17 Q. You think that Prolene mesh shrinks from its 18 pore size to under ten microns?</p> <p>19 A. I think it shrinks from its implanted size to 20 under macroporous.</p> <p>21 Q. I think we said earlier that macroporous was 22 75 microns or greater; is that correct?</p> <p>23 A. Correct.</p> <p>24 Q. And your testimony is that the -- strike that. 25 Your testimony is that the Prolene mesh in the</p>
<p style="text-align: right;">Page 207</p> <p>1 that you can point to that degraded polypropylene mesh 2 increases the inflammatory response?</p> <p>3 A. No.</p> <p>4 Q. Doctor, I believe you stated that you read 5 Ms. Batiste's deposition transcript; is that right?</p> <p>6 A. Yes.</p> <p>7 Q. And you're aware that Ms. Batiste was not 8 provided a patient brochure; is that correct?</p> <p>9 A. Correct.</p> <p>10 Q. And you're aware from Ms. Batiste's testimony 11 that she was not provided any marketing materials from 12 Ethicon; is that correct?</p> <p>13 A. I believe that's accurate.</p> <p>14 Q. You have no independent knowledge -- let me 15 restate that question.</p> <p>16 Doctor, you will not be opining that 17 Ms. Batiste saw a patient brochure from Ethicon; is 18 that correct?</p> <p>19 A. Correct.</p> <p>20 Q. Do you believe that the purpose of a patient 21 brochure is to facilitate a conversation with a patient 22 and the physician?</p> <p>23 A. Well, among other things. I mean, I think the 24 patient brochure should provide accurate information to 25 the patient so the patient can do her research and due</p>	<p style="text-align: right;">Page 209</p> <p>1 TVT contracts below 75 microns in a patient?</p> <p>2 A. I think that's what the internal documents 3 from Ethicon show, correct.</p> <p>4 Q. Doctor, are you aware of any clinical 5 literature that identifies the TVT Prolene mesh 6 contracting from its pore size to below 75 microns?</p> <p>7 A. I don't think that that has been studied in 8 the clinical journals or reported.</p> <p>9 Q. Let me just ask you if this refreshes your 10 recollection or not.</p> <p>11 Have you seen from Ethicon's documents and 12 potentially Dr. Pamela Moalli's document that the pore 13 size for the Prolene mesh is 1379 microns?</p> <p>14 A. I have.</p> <p>15 Q. Do you agree or disagree with that out of the 16 package?</p> <p>17 A. That's what it is claimed.</p> <p>18 Q. And my question to you, Doctor, is do you 19 agree or disagree that the pore size of the Prolene 20 mesh out of the package is 1379 microns, approximately?</p> <p>21 A. I don't recall.</p> <p>22 Q. Doctor, do you know if mechanical cut or laser 23 cut mesh was used in Ms. Batiste's TVT-O implant?</p> <p>24 A. Mechanical.</p> <p>25 Q. Doctor, the Prolene mesh that was used by</p>

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REPORTER'S CERTIFICATE

The undersigned Certified Shorthand Reporter licensed in the State of California does hereby certify:

I am authorized to administer oaths or affirmations pursuant to Code of Civil Procedure, Section 2093(b), and prior to being examined, the witness was duly administered an oath by me.

I am not a relative or employee or attorney or counsel of any of the parties, nor am I a relative or employee of such attorney or counsel, nor am I financially interested in the outcome of this action.

I am the deposition officer who stenographically recorded the testimony in the foregoing deposition, and the foregoing transcript is a true record of the testimony given by the witness.

Before completion of the deposition, review of the transcript [X] was [] was not requested. If requested, any changes made by the deponent (and provided to the reporter) during the period allowed are appended hereto.

In witness whereof, I have subscribed my name this ____ day of _____, 2013.

DIANE S. MARTIN, CSR No. 6464

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INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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E R R A T A

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

MICHAEL THOMAS MARGOLIS, M.D. DATE

Subscribed and sworn to before me this ____ day of _____, 20____.

My commission expires: _____

Notary Public